

TRI-LEVEL CARDIAC CONTROL (CRD CONTROL 1, 2, 3)

CAT. NO. CQ3259 **LOT NO.** 4172CK, 4173CK, 4174CK

SIZE: 3 x 2 ml **EXPIRY:** 2021-07-28

GTIN: 05055273201857

INTENDED USE

This product is intended for *in vitro* diagnostic use in the quality control of Cardiac Markers on clinical chemistry and Immunoassay systems.

DEVICE DESCRIPTION

The Cardiac Controls are supplied at 3 levels, 1, 2 and 3. Target values and ranges are supplied for the following analytes at level 1; CK Total, CKMB Mass, Homocysteine, Myoglobin, Troponin I and Troponin T. Target values and ranges are supplied for the following analytes at level 2 & 3; CK Total, CK-MB (Activity and Mass) Homocysteine, Myoglobin, Troponin I and Troponin T.

SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

Human source material, from which this product has been derived, has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests. However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

Health and Safety Data Sheets are available on request.

STORAGE AND STABILITY

OPENED: Store refrigerated (+2 to +8°C). Reconstituted serum is stable for 5 days at +2°C to +8°C, and 4 weeks at -20°C if kept capped in original container and free from contamination. Troponin I is stable for 2 weeks at -20°C if kept capped in original container and free from contamination. Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

UNOPENED: Store refrigerated (+2 to +8°C). Stable to expiration date printed on individual vials.

PREPARATION FOR USE

The Tri-Level Cardiac Control is supplied lyophilised.

1. Carefully reconstitute each vial of lyophilised serum with exactly 2 ml of redistilled water at +15 to +25°C. Close the bottle and allow to stand for 30 minutes before use. Ensure contents are completely dissolved by swirling gently. Avoid formation of foam. Do not shake.
2. Refer to the Control section of the individual analyser application.
3. Refrigerate any unused material. Prior to reuse, mix contents thoroughly.

MATERIALS PROVIDED

Tri-Level Cardiac Control	Level 1	1 x 2 ml
	Level 2	1 x 2 ml
	Level 3	1 x 2 ml

MATERIALS REQUIRED BUT NOT PROVIDED

Volumetric pipette

ASSIGNED VALUES

Each Batch of Cardiac Control is submitted to a number of external laboratories and values are assigned from a consensus of results obtained by these laboratories and internal testing conducted at Randox Laboratories Ltd. The expected range of the mean is provided to aid laboratory until it has established its own mean and SD for its methods.

If a method is unavailable, contact Randox Laboratories - Technical Services, Northern Ireland, tel: +44 (0) 28 9445 1070 or email Technical.Services@randox.com.

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CARDIAC CONTROL LEVEL 1 (CRD CONTROL 1)

Cat. No. CQ3259 Lot. No. 4172CK Size 1 x 2ml Expiry 2021-07-28

Analyte	unit	Target	Range		methods
			low	high	
CK Total	U/l	65	53	77	CK-NAC substrate start (DGKC) 37°C
	U/l	41	33	49	CK-NAC substrate start (DGKC) 30°C
	U/l	28	23	33	CK-NAC substrate start (DGKC) 25°C
	U/l	94	77	111	Vitros 37°C
	U/l	65	53	77	CK-NAC (IFCC) 37°C
	U/l	41	33	49	CK-NAC (IFCC) 30°C
	U/l	28	23	33	CK-NAC (IFCC) 25°C
CK-MB Mass	ng/ml = µg/l	3.42	2.39	4.45	Siemens Dimension
	ng/ml = µg/l	5.80	4.06	7.54	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	4.68	3.28	6.08	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	5.75	4.03	7.48	Beckman Coulter Access
	ng/ml = µg/l	7.19	5.03	9.35	BioMerieux Vidas
	ng/ml = µg/l	4.26	2.98	5.54	Abbott Architect
	ng/ml = µg/l	5.94	4.16	7.72	Beckman DxI800
	ng/ml = µg/l	1.10	0.770	1.43	Biosite Triage Meter Plus
Homocysteine	µmol/l	10.0	8.00	12.0	Abbott Architect
	µmol/l	13.3	10.6	16.0	Roche Cobas 6000/8000
	µmol/l	15.4	12.3	18.5	Enzymatic
Myoglobin	ng/ml = µg/l	38.1	26.7	49.5	Roche Elecsys
	ng/ml = µg/l	31.7	22.2	41.2	Beckman Coulter Access
	ng/ml = µg/l	33.8	23.7	43.9	BioMerieux Vidas
	ng/ml = µg/l	50.6	35.4	65.8	Abbott Architect
	ng/ml = µg/l	32.2	22.5	41.9	Beckman DxI800
	ng/ml = µg/l	19.3	13.5	25.1	Biosite Triage Meter Plus
	ng/ml = µg/l	61.3	42.9	79.7	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	0.675	0.540	0.810	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	675	540	810	
	ng/ml = µg/l	1.70	1.36	2.04	Ortho Vitros ECi
	ng/l = pg/ml	1700	1360	2040	
	ng/ml = µg/l	2.30	1.84	2.76	Tosoh Series
	ng/l = pg/ml	2300	1840	2760	
	ng/ml = µg/l	0.937	0.750	1.12	Biomerieux Vidas Ultra
	ng/l = pg/ml	937	750	1124	
	ng/ml = µg/l	0.136	0.109	0.163	Beckman DXi800 1st gen
	ng/l = pg/ml	136	109	163	
	ng/ml = µg/l	0.145	0.116	0.174	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	145	116	174	
	ng/ml = µg/l	0.351	0.281	0.421	Mitsubishi Chemical Pathfast
	ng/l = pg/ml	351	281	421	
	ng/ml = µg/l	0.168	0.134	0.202	Siemens Dimension Exl LOCI
ng/l = pg/ml	168	134	202		
ng/ml = µg/l	0.304	0.243	0.365	Abbott Architect STAT hs	
ng/l = pg/ml	304	243	365		

CARDIAC CONTROL LEVEL 1 (CRD CONTROL 1)

Cat. No. CQ3259 Lot. No. 4172CK Size 1 x 2ml Expiry 2021-07-28

Analyte	unit	Target	Range		methods
			low	high	
Troponin I	ng/ml = µg/l	0.151	0.121	0.181	Beckman Dxl - AccuTnl+3
	ng/l = pg/ml	151	121	181	
	ng/ml = µg/l	0.157	0.126	0.188	Beckman Access - AccuTnl+3
	ng/l = pg/ml	157	126	188	
Troponin I	ng/ml = µg/l	1.14	0.912	1.37	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	1140	912	1368	
Troponin T	ng/ml = µg/l	0.058	0.041	0.075	Roche Cobas Troponin T HS
	ng/l = pg/ml	58.0	41.0	75.0	
	ng/ml = µg/l	0.056	0.039	0.073	Roche h232
	ng/l = pg/ml	56.0	39.0	73.0	
Troponin T	ng/ml = µg/l	0.057	0.040	0.074	Roche Cobas Troponin T hs STAT
	ng/l = pg/ml	57.0	40.0	74.0	

CARDIAC CONTROL LEVEL 2 (CRD CONTROL 2)

Cat. No. CQ3259 Lot. No. 4173CK

Size 1 x 2ml Expiry 2021-07-28

Analyte	unit	Target	Range		methods
			low	high	
CK Total	U/l	233	191	275	CK-NAC substrate start (DGKC) 37°C
	U/l	146	120	172	CK-NAC substrate start (DGKC) 30°C
	U/l	99	81	117	CK-NAC substrate start (DGKC) 25°C
	U/l	302	248	356	Vitros 37°C
	U/l	218	179	257	CK-NAC (IFCC) 37°C
	U/l	136	112	161	CK-NAC (IFCC) 30°C
	U/l	93	76	109	CK-NAC (IFCC) 25°C
	U/l	233	191	275	Monothioglycerol 37°C
	U/l	146	120	172	Monothioglycerol 30°C
CK-MB Activity	U/l	20.5	16.4	24.6	Immuno-inhibition substrate start 37°C
	U/l	11.9	9.53	14.3	Immuno-inhibition substrate start 30°C
	U/l	7.28	5.82	8.74	Immuno-inhibition substrate start 25°C
	U/l	20.8	16.6	25.0	Immuno-inhibition serum start 37°C
	U/l	12.1	9.65	14.6	Immuno-inhibition serum start 30°C
	U/l	7.38	5.89	8.87	Immuno-inhibition serum start 25°C
	U/l	19.8	15.8	23.8	Immuno-inhibition (IFCC) 37°C
	U/l	11.5	9.18	13.8	Immuno-inhibition (IFCC) 30°C
	U/l	7.03	5.61	8.45	Immuno-inhibition (IFCC) 25°C
	U/l	20.6	16.5	24.7	Randox Immuno-inhibition substrate start 37°C
	U/l	12.0	9.59	14.4	Randox Immuno-inhibition substrate start 30°C
	U/l	7.31	5.86	8.77	Randox Immuno-inhibition substrate start 25°C
	U/l	20.8	16.6	25.0	Randox Immuno-inhibition serum start 37°C
	U/l	12.1	9.65	14.5	Randox Immuno-inhibition serum start 30°C
	U/l	7.38	5.89	8.88	Randox Immuno-inhibition serum start 25°C
CK-MB Mass	ng/ml = µg/l	16.9	11.8	22.0	Siemens Dimension
	ng/ml = µg/l	22.6	15.8	29.4	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	17.1	12.0	22.2	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	24.3	17.0	31.6	Beckman Coulter Access
	ng/ml = µg/l	26.5	18.6	34.5	BioMerieux Vidas
	ng/ml = µg/l	17.9	12.5	23.3	Abbott Architect
	ng/ml = µg/l	24.7	17.3	32.1	Beckman DxI800
	ng/ml = µg/l	4.78	3.35	6.21	Biosite Triage Meter Plus
Homocysteine	µmol/l	17.0	13.6	20.4	Abbott Architect
	µmol/l	23.9	19.1	28.7	Roche Cobas 6000/8000
	µmol/l	20.6	16.5	24.7	Enzymatic
Myoglobin	ng/ml = µg/l	119	83.3	155	Roche Elecsys
	ng/ml = µg/l	101	70.7	131	Beckman Coulter Access
	ng/ml = µg/l	111	77.7	144	BioMerieux Vidas
	ng/ml = µg/l	164	115	213	Abbott Architect
	ng/ml = µg/l	108	75.6	140	Beckman DxI800
	ng/ml = µg/l	62.1	43.5	80.7	Biosite Triage Meter Plus

CARDIAC CONTROL LEVEL 2 (CRD CONTROL 2)

Cat. No. CQ3259 Lot. No. 4173CK Size 1 x 2ml Expiry 2021-07-28

Analyte	unit	Target	Range		methods
			low	high	
Myoglobin	ng/ml = µg/l	189	132	246	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	0.400	0.320	0.480	Siemens Stratus CS
	ng/l = pg/ml	400	320	480	
	ng/ml = µg/l	3.51	2.81	4.21	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	3510	2810	4210	
	ng/ml = µg/l	7.19	5.75	8.63	Ortho Vitros ECi
	ng/l = pg/ml	7190	5750	8630	
	ng/ml = µg/l	8.52	6.82	10.2	Tosoh Series
	ng/l = pg/ml	8520	6820	10220	
	ng/ml = µg/l	2.75	2.20	3.30	Biomerieux Vidas Ultra
	ng/l = pg/ml	2750	2200	3300	
	ng/ml = µg/l	0.658	0.526	0.790	Beckman DXI800 1st gen
	ng/l = pg/ml	658	526	790	
	ng/ml = µg/l	0.369	0.295	0.443	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	369	295	443	
	ng/ml = µg/l	1.55	1.24	1.86	Mitsubishi Chemical Pathfast
	ng/l = pg/ml	1550	1240	1860	
	ng/ml = µg/l	0.497	0.398	0.596	Siemens Dimension Exl LOCI
	ng/l = pg/ml	497	398	596	
	ng/ml = µg/l	0.991	0.793	1.19	Abbott Architect STAT hs
	ng/l = pg/ml	991	793	1189	
ng/ml = µg/l	0.654	0.523	0.785	Beckman Dxl - AccuTnl+3	
ng/l = pg/ml	654	523	785		
ng/ml = µg/l	0.635	0.508	0.762	Beckman Access - AccuTnl+3	
ng/l = pg/ml	635	508	762		
ng/ml = µg/l	5.41	4.33	6.49	bioMerieux VIDAS hs Troponin I	
ng/l = pg/ml	5410	4330	6490		
Troponin T	ng/ml = µg/l	0.393	0.275	0.511	Roche Cobas Troponin T HS
	ng/l = pg/ml	393	275	511	
	ng/ml = µg/l	0.263	0.184	0.342	Roche h232
	ng/l = pg/ml	263	184	342	
ng/ml = µg/l	0.378	0.265	0.491	Roche Cobas Troponin T hs STAT	
ng/l = pg/ml	378	265	491		

CARDIAC CONTROL LEVEL 3 (CRD CONTROL 3)

Cat. No. CQ3259 Lot. No. 4174CK

Size 1 x 2ml Expiry 2021-07-28

Analyte	unit	Target	Range		methods
			low	high	
CK Total	U/l	795	579	1011	Vitros 37°C
	U/l	600	492	708	CK-NAC (IFCC) 37°C
	U/l	376	308	444	CK-NAC (IFCC) 30°C
	U/l	255	209	301	CK-NAC (IFCC) 25°C
	U/l	629	516	742	Monothioglycerol 37°C
	U/l	394	323	465	Monothioglycerol 30°C
	U/l	267	219	315	Monothioglycerol 25°C
CK-MB Activity	U/l	138	110	166	Immunoinhibition substrate start 37°C
	U/l	80.2	63.9	96.5	Immunoinhibition substrate start 30°C
	U/l	49.0	39.1	58.9	Immunoinhibition substrate start 25°C
	U/l	137	110	164	Immunoinhibition serum start 37°C
	U/l	79.6	63.9	95.3	Immunoinhibition serum start 30°C
	U/l	48.6	39.1	58.1	Immunoinhibition serum start 25°C
	U/l	136	109	163	Immunoinhibition (IFCC) 37°C
	U/l	79.0	63.4	94.6	Immunoinhibition (IFCC) 30°C
	U/l	48.3	38.7	57.9	Immunoinhibition (IFCC) 25°C
	U/l	136	109	163	Randox Immunoinhibition substrate start 37°C
	U/l	79.0	63.4	94.7	Randox Immunoinhibition substrate start 30°C
	U/l	48.3	38.7	57.9	Randox Immunoinhibition substrate start 25°C
	CK-MB Mass	ng/ml = µg/l	189	132	246
ng/ml = µg/l		188	132	244	Siemens Centaur XP/XPT/Classic
ng/ml = µg/l		150	105	195	Roche Elecsys Modular E170 Cobas 6000/e411
ng/ml = µg/l		215	151	280	Beckman Coulter Access
ng/ml = µg/l		153	107	199	Abbott Architect
ng/ml = µg/l		224	157	291	Beckman DxI800
ng/ml = µg/l		40.4	28.3	52.5	Biosite Triage Meter Plus
Homocysteine	µmol/l	35.0	28.0	42.0	Abbott Architect
	µmol/l	53.1	42.5	63.7	Roche Cobas 6000/8000
	µmol/l	36.7	29.4	44.0	Enzymatic
Myoglobin	ng/ml = µg/l	197	138	256	Roche Elecsys
	ng/ml = µg/l	176	123	229	Beckman Coulter Access
	ng/ml = µg/l	203	142	264	BioMerieux Vidas
	ng/ml = µg/l	282	197	367	Abbott Architect
	ng/ml = µg/l	176	123	229	Beckman DxI800
	ng/ml = µg/l	105	73.5	137	Biosite Triage Meter Plus
	ng/ml = µg/l	335	235	436	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	2.02	1.62	2.42	Siemens Stratus CS
	ng/l = pg/ml	2020	1620	2420	
	ng/ml = µg/l	23.8	19.0	28.6	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	23800	19000	28600	

CARDIAC CONTROL LEVEL 3 (CRD CONTROL 3)

Cat. No. CQ3259 Lot. No. 4174CK Size 1 x 2ml Expiry 2021-07-28

Analyte	unit	Target	Range		methods
			low	high	
Troponin I	ng/ml = µg/l	32.8	26.2	39.4	Ortho Vitros ECI
	ng/l = pg/ml	32800	26200	39400	
	ng/ml = µg/l	36.0	28.8	43.2	Tosoh Series
	ng/l = pg/ml	36000	28800	43200	
	ng/ml = µg/l	11.0	8.80	13.2	Biomerieux Vidas Ultra
	ng/l = pg/ml	11000	8800	13200	
	ng/ml = µg/l	4.68	3.74	5.62	Beckman DXi800 1st gen
	ng/l = pg/ml	4680	3740	5620	
	ng/ml = µg/l	1.37	1.10	1.64	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	1370	1100	1640	
	ng/ml = µg/l	9.81	7.85	11.8	Mitsubishi Chemical Pathfast
	ng/l = pg/ml	9810	7850	11770	
	ng/ml = µg/l	2.33	1.86	2.80	Siemens Dimension Exl LOCI
	ng/l = pg/ml	2330	1860	2800	
	ng/ml = µg/l	5.18	4.14	6.22	Abbott Architect STAT hs
	ng/l = pg/ml	5180	4140	6220	
ng/ml = µg/l	4.58	3.66	5.50	Beckman Dxl - AccuTnl+3	
ng/l = pg/ml	4580	3660	5500		
ng/ml = µg/l	4.53	3.62	5.44	Beckman Access - AccuTnl+3	
ng/l = pg/ml	4530	3620	5440		
ng/ml = µg/l	30.9	24.7	37.1	bioMerieux VIDAS hs Troponin I	
ng/l = pg/ml	30900	24700	37100		
Troponin T	ng/ml = µg/l	1.090	0.763	1.420	Roche Cobas Troponin T HS
	ng/l = pg/ml	1090	763	1417	
	ng/ml = µg/l	0.688	0.482	0.894	Roche h232
	ng/l = pg/ml	688	482	894	
	ng/ml = µg/l	1.070	0.749	1.390	Roche Cobas Troponin T hs STAT
	ng/l = pg/ml	1070	749	1391	